



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ensystex IV, Inc.; 2175 Village Drive, Fayetteville, NC 28304; (253) 853-7369	EPA Registration Number/File Symbol 83923-xx
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Bifenthrin	Date April 16, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Nonfood, Domestic Outdoor	Product Name Bithor XT

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

4/16/15

Typed or Printed Name and Title


P. Leanne Pruett, Agent

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DATA MATRIX


Date April 16, 2015			EPA Reg No./File Symbol 83923-X		Page 1 of 4
Applicant's/Registrant's Name & Address Ensystex IV, Inc. 2175 Village Drive Fayetteville, NC 28304			Product Bithor XT		
Ingredient Imidacloprid, Bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements – Product Chemistry					
830.1550	Product Identity and Composition	46969301	Ensystex IV, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	46969301	Ensystex IV, Inc.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	46969301	Ensystex IV, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	46969301	Ensystex IV, Inc.	OWN	
830.1700	Preliminary Analysis				Not required ²
830.1750	Certified Limits	46969301	Ensystex IV, Inc.	OWN	
830.1800	Enforcement Analytical Method	46969301	Ensystex IV, Inc.	OWN	
830.6302	Color				Not required ³
830.6303	Physical State	46969302	Ensystex IV, Inc.	OWN	
830.6304	Odor				Not required ³
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	46969302	Ensystex IV, Inc.	OWN	
830.6315	Flammability				Not required ⁴
830.6316	Explosibility				Not required ⁵
Signature 			Name and Title P. Leanne Pruett, Consultant		Date 4/16/2015

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DATA MATRIX


Date April 16, 2015			EPA Reg No./File Symbol 83923-X		Page 2 of 4
Applicant's/Registrant's Name & Address Ensyslex IV, Inc. 2175 Village Drive Fayetteville, NC 28304			Product Bithor XT		
Ingredient Imidacloprid, Bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	47241001	Ensyslex IV, Inc.	OWN	
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	47241001	Ensyslex IV, Inc.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	46969302	Ensyslex IV, Inc.	OWN	
830.7050	UV/Visible Absorption				Not required ³
830.7100	Viscosity	46969302	Ensyslex IV, Inc.	OWN	
830.7200	Melting Point/Melting Range				Not required ³
830.7220	Boiling Point/Boiling Range				Not required ³
830.7300	Density/Relative Density/Bulk Density	46969302	Ensyslex IV, Inc.	OWN	
830.7370	Dissociation Constants in Water				Not required ³
830.7520	Particle size, fiber length, diameter distribution				Not required ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ³
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				Not required ³
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				Not required ³
Signature 			Name and Title P. Leanne Pruett, Consultant		Date 4/16/2015

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Applicant's/Registrant's Name & Address Ensystem IV, Inc. 2175 Village Drive Fayetteville, NC 28304			Product Bithor XT		
Ingredient Imidacloprid, Bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ³
830.7860	Water Solubility, Generator Column Method				Not required ³
830.7950	Vapor Pressure				Not required ³
Product Specific Data Requirements – Acute Toxicity					
870.1100	Acute Oral Toxicity: Rat	49484901	Ensystem IV, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	49484902	Ensystem IV, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	49484903	Ensystem IV, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	49484904	Ensystem IV, Inc.	OWN	
870.2500	Primary Dermal Irritation	49484905	Ensystem IV, Inc.	OWN	
870.2600	Dermal Sensitization	49484906	Ensystem IV, Inc.	OWN	
Product Specific Data Requirements - Efficacy					
810.3100	Soil Treatments for Imported Fire Ants	44638801	FMC Corp.	OLD	
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments	44891904 46393501	FMC Corp. FMC Corp.	OLD PER	
Signature 			Name and Title P. Leanne Pruett, Consultant		Date 4/16/2015

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Applicant's/Registrant's Name & Address Ensyslex IV, Inc. 2175 Village Drive Fayetteville, NC 28304			Product Bithor XT		
Ingredient Imidacloprid, Bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3500	Premises Treatments	44137401	FMC Corp.	OLD	
		44137402	FMC Corp.	OLD	
		44891903	FMC Corp.	OLD	
		44891906	FMC Corp.	OLD	
		44891907	FMC Corp.	OLD	
		44891908	FMC Corp.	OLD	
		49484907	Ensyslex IV, Inc.	OWN	
810.3600	Structural Treatments	44891903	FMC Corp.	OLD	
		44891906	FMC Corp.	OLD	
		44891907	FMC Corp.	OLD	
		44891908	FMC Corp.	OLD	
		49484907	Ensyslex IV, Inc.	OWN	
Imidacloprid and Bifenthrin Generic Data Requirements					
Ensyslex IV, Inc. qualifies for Formulator's Exemption for imidacloprid and bifenthrin generic data requirements.					
Signature 			Name and Title P. Leanne Pruett, Consultant		Date 4/16/2015

Endnotes for Data Matrix for Bithor XT

April 16, 2015

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- ¹ **830.1620** - Per OPPTS 830.1000, these data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** – This product does not consist solely of the technical grade active ingredient (TGA) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6302, 830.6304, 830.6313, 830.7050, 830.7200, 830.7220, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860 and 830.7950** – Per OPPTS 830.1000, these data are not required for the registration of an end-use product.
- ⁴ **830.6315** - This product is not a combustible liquid; therefore these data are not applicable to this end-use product. Please refer to the Confidential Statement of Formula for additional information on the composition of Bithor XT.
- ⁵ **830.6316** – This product does not have explosive characteristics; therefore these data are not required. Please refer to the Confidential Statement of Formula for additional information on the composition of Bithor XT.
- ⁶ **830.6319** – Bithor XT is a suspension concentrate formulation and not an emulsifiable concentrate. In addition, the proposed label recommends dilution of Bithor XT with water, not oil; therefore, these data are not applicable nor are these data required.
- ⁷ **830.6321** – This product is not proposed for use around electrical equipment. Therefore, these data are not applicable nor are these required.
- ⁸ **830.7520** - These data are not required for Bithor XT because it is not water insoluble and is not a fibrous material.